

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation, <i>et al.</i>)	
)	
Defendants.)	
)	

DEFENDANTS' OPPOSITION TO MITEK'S MOTION TO STRIKE DR.
MUKHERJEE'S DECLARATIONS AND EXHIBITS

Dated: October 6, 2006

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I. INTRODUCTION

Defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Ltd. (“Pearsalls”) (together, “defendants”) submit this Opposition to DePuy Mitek’s Motion to Strike Dr. Mukherjee’s Declarations and Exhibits (“Mitek Mot. to Str.”). Defendants recently submitted two declarations from their expert, Dr. Mukherjee, to which DePuy Mitek now objects. The first declaration supports defendants’ summary judgment/*Markman* positions (“Mukherjee SJ/*Markman* Dec.”), and was submitted along with defendants’ Reply in support of their Motion for Summary Judgment (as Ex. 23, thereto) and also submitted along with defendants’ Reply in support of their Opening Brief on Claim Construction (as Ex. 1, thereto). The second declaration supports, and was submitted with, defendants’ opposition to DePuy Mitek’s motion to strike the Spectra brochure as hearsay (“Mukherjee Spectra Dec.”) (as Ex. 3, thereto).

As explained below, both of these declarations were submitted in response to DePuy Mitek’s actions in this case. Dr. Mukherjee’s SJ/*Markman* declaration was submitted only after DePuy Mitek denied statements made by *its own* expert (Dr. Brookstein), only after it presented a new argument for the first time in its opposition to summary judgment, and only after its expert, Dr. Hermes, asserted a new argument in his last rebuttal report (without giving Dr. Mukherjee an opportunity to respond). Dr. Mukherjee’s Spectra declaration was submitted only after DePuy Mitek filed its improbable motion challenging the authenticity and admissibility of the Spectra brochure -- a document DePuy Mitek produced from *its own files* in response to a document request from defendants.

In what has clearly surfaced as DePuy Mitek’s modus operandi, it tries to refute the irrefutable (*e.g.*, statements clearly made by its own expert, the authenticity of its own documents, etc.), thereby forcing defendants to re-prove, by other evidence, the same facts defendants believed were already established in this case, and then DePuy Mitek seeks to

exclude defendants from presenting that evidence with crocodile tears and claims that defendants are too late.

But that is not all. As mentioned above, DePuy Mitek also tries to unfairly sneak in new arguments at the last minute -- in both its expert's report and in its opposition to summary judgment -- and when defendants rightfully respond to those new arguments, DePuy Mitek again seeks to exclude any responsive evidence presented by defendants as untimely. To the extent DePuy Mitek has any objections to Dr. Mukherjee's declarations, it has only itself to blame, for Dr. Mukherjee's declarations are offered to defend against DePuy Mitek's own new arguments. DePuy Mitek should not be permitted to continue this disturbing pattern of manipulation. For the reasons explained below, its motion should be denied.

II. DR. MUKHERJEE'S SUMMARY JUDGMENT/MARKMAN DECLARATION BECAME APPROPRIATE ONLY AFTER DEPUY MITEK'S UNFAIR ACTIONS IN THIS CASE AND IS REPOSITIVE THERETO

DePuy Mitek objects to Dr. Mukherjee's *SJ/Markman* declaration, but it was DePuy Mitek's own unfair actions in this case that necessitated such a response from Dr. Mukherjee and defendants. Those unfair actions include:

i) DePuy Mitek's denial that *its own* expert's report included statements acknowledging that UHMWPE is stiff and unpliant;

ii) DePuy Mitek's questioning the authenticity, and objecting to the admissibility, of the Spectra brochure produced from *its own* files;

iii) DePuy Mitek asserting *for the first time*, in its opposition to summary judgment, a new argument that the '575 patent can not be an anticipating reference since it does not disclose sterilization; and

iv) DePuy Mitek's expert stating in his last rebuttal expert report (without an opportunity for Dr. Mukherjee to respond) that "PE" is not weak in tension.

As we show below, Dr. Mukherjee's *SJ/Markman* declaration is a perfectly appropriate response.

A. Evidence on the Stiffness of UHMWPE Became Appropriate Only After DePuy Mitek Denied That its Expert Acknowledged That Well-Known Fact

In both their Motion for Summary Judgment ("Def's SJ Mot.") and their Opening Brief on Claim Construction ("Def's *Markman* Br."), defendants cited to the expert report of Dr. Brookstein, *DePuy Mitek's expert*, in which he acknowledged that UHMWPE is stiff and not pliable. Def's SJ Mot. at 11; Def's *Markman* Br. at 11. DePuy Mitek, however, tried to deny Dr. Brookstein's acknowledgement in its Response to Defendants' Opening Brief on Claim Construction ((*"Mitek's Markman Response"*) at 9, n.6)), leaving defendants no choice but to present additional evidence proving the well-known fact that UHMWPE is stiff and not pliable. When defendants presented that evidence, DePuy Mitek could not and did not deny the accuracy of the evidence. Instead, and quite predictably, DePuy Mitek objects to defendants' evidence.

DePuy Mitek cannot have it both ways. DePuy Mitek cannot deny undeniable statements made in its own expert's report, in which Dr. Brookstein acknowledged that UHMWPE is stiff and not pliable, and then object when defendants are forced to present other evidence to prove a fact that everyone in the field -- including Dr. Brookstein -- already knows. That is grossly unfair.

B. Submitting Evidence of the Relative Strengths of UHMWPE and General Purpose PE Became Appropriate After DePuy Mitek Questioned the Authenticity and Objected to the Admissibility of the Spectra Brochure Produced From Its Own Files

In their Motion for Summary Judgment and in their Opening Brief on Claim Construction, defendants presented the Spectra brochure as evidence of the great difference in strength between UHMWPE and general purpose PE. Def's SJ Mot. at 1; Def's *Markman* Br. at 1, 14. The Spectra brochure also evidences the fact that this great difference in strength is well-known in the polymer fiber industry. Notably, DePuy Mitek produced the Spectra brochure from *its own* files in response to defendants' document request. Thus, defendants had no reason to

believe DePuy Mitek would ever challenge the authenticity or the admissibility of the document. After all, not only did DePuy Mitek produce the document from its own files, but it also sat by and watched as two of its witnesses -- Shelby Cook and Dr. Hermes -- were questioned at deposition regarding the document as early as November 2005. Ex. 1 at 193:10-23; Ex. 2 at 314:14-315:4.

As the Court is aware, DePuy Mitek has now, at this late date, objected to the admissibility of the same Spectra brochure it produced from *its own* files. As defendants explained in their opposition to DePuy Mitek's motion to strike the Spectra brochure as hearsay ("Def's Hearsay Opp."), the Spectra brochure was produced by DePuy Mitek more than a year ago, on June 21 2005, and it bears the DePuy Mitek bates number range "DMI003378-3390. Def's Hearsay Opp. at 3. Thus, the Spectra brochure is admissible at least as a business record. Def's Hearsay Opp. at 3-4.¹

Although defendants strongly believe that the Spectra brochure is admissible, defendants were faced with a situation where its evidence was being challenged. It is because defendants were faced with that potential risk -- due entirely to DePuy Mitek's improbable challenge of a document it produced -- that defendants are forced to offer *other* evidence showing the great difference in strength between UHMWPE and general purpose PE. Again, DePuy Mitek predictably does not challenge the accuracy of Dr. Mukherjee's evidence. Rather, it tries to play a game of "gotcha" -- you can't use the evidence you submitted and can't submit anything further. DePuy Mitek wants to have it both ways, but it cannot, and should not be allowed to do so.

¹ Defendants also describe why the Spectra brochure is admissible under any one of several other grounds -- as a commercial publication, as a learned treatise, under the residual hearsay exception, and/or since it is offered by defendants, at least in part, for non-hearsay purposes. Def's Hearsay Opp. at 4-8

C. Evidence that Sterilization of Suture Prior to Its Use is Well-Known in the Surgical Suture Art Became Appropriate Only After DePuy Mitek Presented For the First Time Its Argument That the '575 Patent is Not an Anticipating Reference Since it Does Not Expressly Disclose Sterilization

Although DePuy Mitek has known that defendants have been asserting the '575 patent as an anticipating reference since early 2004, DePuy Mitek waited until last month, in its Opposition to defendants' summary judgment motion, to assert a new argument that the '575 patent is not an anticipating reference because it does not mention sterilization. Mitek SJ Opp. at 24-25. DePuy Mitek could have asserted this new argument during fact discovery in its interrogatory responses, yet it did not. DePuy Mitek also could have asserted this new argument in its expert reports that considered the '575 patent, but it again failed to do so. If anyone should be precluded, it is DePuy Mitek, not defendants, who is raising an argument at the last minute.

Yet, in DePuy Mitek's world, it should be allowed to present this new argument, for the first time, in its opposition to summary judgment, and defendants should be precluded from responding to this new argument. This is the height of hypocrisy, and is totally unfair. It is also why DePuy Mitek's motion should be denied.

D. Evidence of the Relative Strengths of UHMWPE and General Purpose PE Became Appropriate After Dr. Hermes Stated in His Rebuttal Expert Report That PE is Not Weak in Tension

In his rebuttal expert report, Dr. Hermes stated that "PE" is not weak in tension. Ex. 3 at ¶ 50. Since Dr. Hermes waited until his rebuttal report to make this statement, and since, by that time, Dr. Mukherjee had no chance to respond to this statement, defendants responded to the statement in their Motion for Summary Judgment and their Opening Brief on Claim Construction. They responded, at least in part, by citing portions of the Spectra brochure describing the great difference in strength between general purpose (or commodity type) PE and UHMWPE. Def's Mot. for SJ at 1; Def's *Markman* Br. at 1, 14. Here again, DePuy Mitek tries to have it both ways. It cannot present arguments, through its expert, Dr. Hermes, only after it is too late for Dr. Mukherjee to respond, and then seek to prevent defendants from responding to those arguments.

E. Dr. Mukherjee Could Not Reasonably Anticipate DePuy Mitek's Above-Described Actions

DePuy Mitek apparently takes the position that Dr. Mukherjee should have included the statements from his *SJ/Markman* declaration in his expert reports served in March and April 2006. Mitek Mot. to Str. at 3-5. Yet, as explained above, Dr. Mukherjee's *SJ/Markman* declaration only became necessary to respond to specific DePuy Mitek actions that occurred only recently in this case. DePuy Mitek never does explain how Dr. Mukherjee should have been able to anticipate DePuy Mitek's actions which did not occur until months later. The answer, of course, is that Dr. Mukherjee could not reasonably have anticipated DePuy Mitek's actions in March and April 2006. Dr. Mukherjee's *SJ/Markman* declaration was timely filed, and without any undue delay, after it became appropriate due to DePuy Mitek's actions.

In any event, there is nothing unusual about Dr. Mukherjee's subsequent declarations in response to additional developments in the case. Dr. Mukherjee, in his expert reports, specifically reserved the right to offer additional opinions both in response to new arguments or opinions that DePuy Mitek might raise or if additional information came to his attention. Ex. 4 at 2-3; Ex. 5 at 3; Ex. 6 at 2. Even if everything asserted in DePuy Mitek's motion were correct – and it decidedly is not – the most that could be said is that Dr. Mukherjee is providing the additional information that he indicated might occur. Nor can DePuy Mitek legitimately assert any surprise at such routine actions. Its own experts made similar statements in their expert reports. Ex. 7 at 10; Ex. 8 at 9.

III. DR. MUKHERJEE'S SPECTRA DECLARATION BECAME APPROPRIATE ONLY AFTER DEPUY MITEK QUESTIONED THE AUTHENTICITY OF, AND CHALLENGED THE ADMISSIBILITY OF, THE SPECTRA BROCHURE PRODUCED FROM ITS OWN FILES

As mentioned above, DePuy Mitek has objected to the admissibility of the Spectra brochure produced from *its own* files, which it produced to defendants more than a year ago. Importantly, Dr. Mukherjee's Spectra declaration only became necessary because DePuy Mitek filed its motion to exclude the Spectra brochure as hearsay. Yet DePuy Mitek takes the position

that defendants cannot submit evidence to respond to that motion. Any such position is preposterous, and is not the law.

The simple fact is that Dr. Mukherjee's Spectra declaration was submitted for the purpose of demonstrating that the Spectra brochure is not inadmissible hearsay. Defendants responded to the motion and explained that the Spectra brochure is admissible under at least four different exceptions to the hearsay rule (*i.e.*, as a business record, as a commercial, as a learned treatise, under the residual hearsay exception, and/or since it is offered by defendants, at least in part, for non-hearsay purposes). Def's Hearsay Opp. at 4-8. Defendants submitted Dr. Mukherjee's Spectra declaration as expert testimony to establish that statements in the Spectra brochure are admissible under the learned treatise exception to the hearsay rule (FED. R. EVID. 804(18)). Def's Hearsay Opp. at 5-6. That is the reason why the Spectra declaration is appropriate and why DePuy Mitek's motion should be denied.²

Finally, in an effort to convince the Court that there is surprise where none exists, DePuy Mitek asserts that the Spectra brochure "first appeared" on July 25, 2006. DePuy Mitek knows this is not true. The Spectra brochure was produced by DePuy Mitek more than a year earlier than that, and it was first introduced by defendants at the depositions of Shelby Cook, in November 2005 – almost a year ago. In light of these facts, any claim of "surprise" by DePuy Mitek is wholly without merit.³

² DePuy Mitek again takes the position that Dr. Mukherjee should have included the statements from his Spectra declaration in his expert reports, prepared in March and April 2006. Mitek Mot. to Str. at 5. Yet, as explained above, Dr. Mukherjee's Spectra declaration became appropriate only after DePuy Mitek decided to challenge the authenticity and admissibility of a document produced from *its own* files. This is something that simply could not reasonably have been anticipated by defendants.

³ DePuy Mitek states that the Spectra brochure was one of about 95,000 pages of documents it produced in this case. Mitek Mot. to Str. at 3. But, the Spectra brochure is one of only 214 exhibits defendants have introduced at depositions in this case. As stated above, the Spectra brochure was introduced at deposition early on in this case – in fact, it was the 20th exhibit marked by defendants.

IV. **DEPUY MITEK IS NOT UNDULY PREJUDICED BY DR. MUKHERJEE'S DECLARATIONS**

As defendants stated in their opposition to DePuy Mitek's motion to strike the Spectra brochure, DePuy Mitek cannot assert that it will somehow be unduly prejudiced by Dr. Mukherjee's declarations because it will have the opportunity to cross examine Dr. Mukherjee at trial and it will also have the opportunity to elicit, from its own experts, additional testimony about the Spectra brochure as well as about exhibits B-E to Dr. Mukherjee's declarations. *See, e.g., Caruolo v. John Crane, Inc.*, 226 F.3d 46, 55 (2nd Cir. 2000) (even though first mention of the study was not until expert's re-direct testimony at trial, admission of the study was not overly prejudicial since there was opportunity to cross examine expert and to elicit additional testimony from objecting parties' own expert).

Much to the contrary, it would be defendants who are unduly prejudiced if DePuy Mitek is permitted to continue this pattern of manipulation -- running away from the statements of its own expert, challenging the authenticity and admissibility of a document produced from *its own* files, and presenting new arguments *for the first time* in its expert's rebuttal report and in its summary judgment opposition, without allowing defendants an opportunity to respond. Dr. Mukherjee's declarations were prepared only in response to these actions by DePuy Mitek. It would be defendants, not DePuy Mitek, that would be prejudiced if DePuy Mitek's motion were granted.⁴

⁴ DePuy Mitek also asserts that Dr. Mukherjee should not be permitted to "supplement" his expert report. Mitek Mot. to Str. at 7-9. Dr. Mukherjee's declarations, however, are not a supplement to his reports. Rather, he, and defendants, are simply responding to DePuy Mitek's new arguments.

Even if Dr. Mukherjee's declarations were considered a "supplement" to his earlier reports, they are still appropriate. DePuy Mitek misstates the law and would have this Court believe that the law provides for some narrow "exception" by which an expert report "may" be supplemented. That is not the law. According to Rule 26(e)(1), "a party is under a *duty* to supplement" an expert report "if the party learns that in some material respect the information disclosed is incomplete or incorrect." [Emphasis added.] The supplementation is timely as long as it is made at least 30 days before trial (Fed. R. Civ. P. 26(e)(1), 26(a)(3)), as plainly is the case here. Accordingly, even if DePuy Mitek's characterization is correct, the rules permit Dr. Mukherjee to supplement his opinions.

V. CONCLUSION

For all the foregoing reasons, DePuy Mitek's motion should be denied.

Dated: October 6, 2006

Respectfully submitted,

By: /s/Charles W. Saber
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Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS' OPPOSITION TO MITEK'S MOTION TO STRIKE DR. MUKHERJEE'S DECLARATIONS AND EXHIBITS was served, via the Court's email notification system on the following counsel for Plaintiff on the 6th day of October 2006:

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/s/Charles W. Saber

EXHIBIT 1

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 C.A. No. 04-12457 PBS

4 * * * * *

COPY

5 DePUY MITEK, INC.,

6 Plaintiff

7 v.

8 ARTHREX, INC., a Delaware

9 corporation,

10 Defendant

11 * * * * *

12 VOLUME I

13 PAGES 1-245

14

15 DEPOSITION OF DePUY MITEK, INC. by
16 SHELBY COOK KORNBLUTH, a witness called on
17 behalf of the Defendant, pursuant to the
18 Federal Rules of Civil Procedure, before
19 Jessica L. Williamson, Registered Merit
20 Reporter, Certified Realtime Reporter and
21 Notary Public in and for the Commonwealth of
22 Massachusetts, at the Hilton Hotel, 25
23 Allied Drive, Dedham, Massachusetts, on
24 Tuesday, November 15, 2005, commencing at
25 9:01 a.m.

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 193

1 A. But I understand the document.

2 **Q. Right. And was this document part of the**
3 **development project of Orthocord?**

4 A. Yes.

5 MR. SABER: This is Exhibit 20.

6 (Exhibit No. 20, Document bearing
7 Production Nos. DMI003378 - 003390, marked
8 for identification.)

9 (Discussion off the record.)

10 **Q. Let me show you what's been marked as**
11 **Defendant's Exhibit 20, and ask if you're**
12 **familiar with that.**

13 A. Can you please expand that?

14 **Q. Yeah. Are you familiar with Defendant's**
15 **Exhibit 20?**

16 A. I have not seen this before, no.

17 **Q. Do you know who -- does SPECTRA mean**
18 **anything to you?**

19 A. Yes.

20 **Q. What is SPECTRA?**

21 A. SPECTRA is an ultra high molecular weight
22 polyethylene fiber that is manufactured by
23 Honeywell, or AlliedSignal now.

24 **Q. Could you look at the page that says**
25 **DMI003380.**

EXHIBIT 2

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

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1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

		Page 314
1	little break.	12:24:33p
2	MR. BONELLA: Okay.	12:24:34p
3	THE VIDEOGRAPHER: Going off the	12:24:35p
4	record; the time on the video monitor is 12:23	12:24:36p
5	P.M.	12:24:40p
6	(A recess was had from 12:23	12:24:45p
7	P.M. to 12:36 P.M.; and then the proceedings	12:24:45p
8	continued as follows:)	12:24:45p
9	THE VIDEOGRAPHER: Going back on	12:36:53p
10	the record. The time on the video monitor is	12:36:55p
11	12:36 P.M.	12:36:58p
12	Please continue.	12:37:00p
13	BY MR. SABER:	12:37:03p
14	Q. Dr. Hermes, let me hand you what has	12:37:03p
15	been previously marked as Defendant's Exhibit-20.	12:37:06p
16	MR. BONELLA: Thank you.	12:37:13p
17	BY MR. SABER:	12:37:14p
18	Q. Have you ever seen this document	12:37:14p
19	before, sir?	12:37:21p
20	A. I don't believe so.	12:37:29p
21	Q. Are you familiar with the product	12:37:30p
22	Spectra?	12:37:35p
23	A. To some extent, Mr. Saber, yes.	12:37:42p
24	Q. Is it your understanding that Spectra	12:37:44p
25	is a fiber made of ultra high molecular weight	12:37:47p

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

		Page 315
1	polyethylene?	12:37:52p
2	MR. BONELLA: Object to form.	12:37:53p
3	THE WITNESS: Yes, that is my	12:37:53p
4	understanding.	12:37:54p
5	BY MR. SABER:	12:37:55p
6	Q. Now, could you see in the -- why don't	12:37:55p
7	you -- well, never mind.	12:38:08p
8	Do you see there's a reference	12:38:11p
9	near the end of the second paragraph, on the	12:38:21p
10	first -- it's the third page of the exhibit, the	12:38:26p
11	first page of text, near the end of the second	12:38:29p
12	paragraph there is a reference to the term	12:38:35p
13	commodity-type polyethylene (PE)?	12:38:41p
14	A. I do see that, yes.	12:38:48p
15	Q. Do you have -- have you ever heard the	12:38:50p
16	term commodity-type polyethylene?	12:38:52p
17	A. Oh, I'm sure I have. I don't -- I	12:38:55p
18	can't recall in what context.	12:38:57p
19	Q. Do you have an understanding of what	12:39:05p
20	commodity-type polyethylene is?	12:39:07p
21	A. No, I don't. You know, this is a --	12:39:11p
22	this is an advertising brochure by Allied Fibers,	12:39:15p
23	Allied Signal, and I'm sure they have a meaning	12:39:20p
24	in their own mind and are trying to make a point,	12:39:22p
25	but I don't know what the point is, sir.	12:39:25p

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Civil No. 04-12457 PBS

Arthrex, Inc.
a Delaware Corporation and

Pearsalls Ltd.,
a Private Limited Company
of the United Kingdom,

Defendants.

Rebuttal Expert Report of Dr. Matthew Hermes

I. Scope of Opinion

1. I have been asked to provide an opinion about certain aspects of the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-infringement of U.S. Patent No. 5,314,446 and Other Matters." Specifically, I have been asked to opine on Dr. Mukherjee's opinion of the validity of claim 9 of the 446 patent.
2. I have also been asked to provide an opinion about certain aspects of the "Expert Report of Rodney J. Bosco, AVA." Specifically, I was asked to opine on Mr. Bosco's opinion that Arthrex's proposed design-around options were commercially available.
3. I have also been asked to review the testing described in Ex. 19 to Dr. Mukherjee's responsive report and provide my opinions regarding this test.
4. A list of the documents I have considered is attached as Ex. 28.

V. UHMWPE Is Described In the 446 Patent To One of Ordinary Skill In the Art in February 1992

48. I disagree with Dr. Mukherjee's opinion that the 446 patent use of the term "PE" or "polyethylene" would not have conveyed to one of ordinary skill in the art that the inventors were in possession of an invention that included UHMW PE. My previous report explains why I disagree with Dr. Mukherjee, but I address a few additional points that he raises here.

49. Dr. Mukherjee states that the first-fiber materials disclosed in the 446 patent are described as too "weak" for most suture applications. I disagree with that statement (Mukherjee Res. Rpt. at 7). As I explained in my previous report, the 446 patent does not state this.

50. I have reviewed Dr. Brookstein's report concerning the description of the first fiber forming materials and his response to Dr. Mukherjee's statements that the 446 Patent describes the first fiber forming materials as "weak." Assuming that he means, "weak" in tensile strength, I agree with Dr. Brookstein that the 446 patent does not describe the first fiber-forming materials as "weak." I have reviewed Exs. J, K, L, M, and N to Dr. Brookstein's report and agree that at least some of the first fiber-forming materials, including at least some PE, PP, PVDF (polyvinylidene fluoride) materials, are not "weak" in tension. This supports my opinion that the first fiber-forming materials are not described as "weak." Therefore, because at least some of the first fiber-forming materials are not "weak" in tension, one of skill in the art between 1988 and 1992 would not have understood the 446 Patent to disclose the first fiber-forming materials as being a group of "weak" materials. Accordingly, one of skill in the art between 1988 and 1992

would have understood the 446 patent to disclose UHMW PE by its reference to the generic name "PE."

51. Further, I was responsible for the extrusion, drawing and heat-setting of polypropylene fibers for sutures and know that polypropylene fibers are not considered "weak" fibers. While I directed suture development at U.S. Surgical we developed, manufactured and sold SURGIPRO 100% polypropylene monofilament sutures. From my own experience, 100% polypropylene monofilament sutures are not considered weak.

52. Dr. Mukherjee cites to the statement in the 446 patent that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid" as meaning that the first-fiber forming yarns are "too weak for most suture applications." I disagree with his analysis. The statement does not mean that all the first fiber-forming materials are too weak for "most suture applications." Rather, the statement refers to a specific variation of a "most preferred embodiment" of a suture having a braid of PTFE and PET. The patent describes that the strength of a suture having a PTFE/PET braid and a PTFE core may be adversely affected, if the PTFE is more than 80% by volume, because too much of the lubricous yarn in the braid may adversely affect strength. Thus, I disagree because that statement is describing a single embodiment using PTFE and is not describing that all first-fiber forming materials as "too weak for most suture applications" as Dr. Mukherjee states. It does not even refer to other suture applications.

53. According to Dr. Mukherjee, column 2, lines 22-25 of the 446 patent states that "braids of highly lubricous polymers' will be highly pliable but they will also be relatively

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. and Pearsalls, Ltd. (together "Defendants") to review U.S. Patent No. 5,314,446 ("the '446 patent") and certain other materials, and to provide my opinion on issues relating to: i) whether claims of the '446 patent are invalid as anticipated by prior art, ii) whether claims of the '446 patent are invalid as obvious in view of prior art, iii) whether claims of the '446 patent are invalid for not satisfying the written description and/or enablement requirements under 35 U.S.C. § 112 and iv) whether inventions claimed in the '446 patent were actually reduced to practice prior to the February 19, 1992 filing date. From a review of DePuy Mitek's interrogatory answers, I understand that claims 1, 2, 8 and 12 are being asserted against Defendants in this case ("the asserted claims"). I am being compensated at a rate of \$1000.00 per day.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of these issues, any matters set forth in this report, and rebuttal of any matters raised by Plaintiff DePuy Mitek. This report includes my opinions regarding these matters. I specifically reserve the right to formulate and offer additional opinions based on any responsive reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or

during trial. Opinions formed are covered below in Section VI. Documents reviewed and considered are identified in Section III and Ex. 1.

II. SUMMARY OF MY OPINIONS

Based upon my review and consideration of the materials identified in Exhibit 1, it is my opinion that U.S. Patent No. 4,610,688, ("the '688 patent"), when combined with U.S. Patent No. 5,120,802 ("the '802 patent"), and/or the general teachings of the art, includes every limitation of the asserted claims of the '446 patent (i.e., claims 1, 2, 8 and 12), and that there was a motivation or suggestion to make these combinations at the time of the '446 patent inventions.

I understand that DePuy Mitek is asserting in this case that the ultra high molecular weight polyethylene ("UHMWPE"), as used in Arthrex's FiberWire suture, is included in "PE," as claimed in the '446 patent. I disagree with that position, however, in the event that the Court were to determine that UHMWPE does fall within the meaning of PE, as claimed in the '446 patent, then I have comments on several other pieces of prior art that are relevant to the anticipation or obviousness inquiries.

For example, in the event that the claims of the '446 patent are construed by the Court to include UHMWPE, it is my opinion that U.S. Patent No. 5,318,575 ("the '575 patent") includes every limitation of the asserted claims of the '446 patent.

Further, it is my opinion that if the Court were to construe the claims of the '446 patent to include UHMWPE, the combination of UK Patent Application No. 2,218,312A

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446
AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of these issues, any matters set forth in this report, and rebuttal of any matters raised by Plaintiff DePuy Mitek. This report includes my opinions regarding these matters. I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial. Opinions formed are covered below in Section VI. Documents reviewed and considered are identified in Section III and Ex. 1.

II. SUMMARY OF MY OPINIONS

Based upon my review and consideration of the materials identified in Ex. 1, it is my opinion that a person of ordinary skill in the art, in February 1992, would not understand the term "PE," as described and claimed in the '446 patent, to include UHMWPE.

It is also my opinion that a person of ordinary skill in the art, in February 1992, would have understood the basic and novel characteristics of the invention described and claimed in the '446 patent to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his rebuttal expert report as follows.

I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together "Defendants") to review the Expert Report of Dr. Matthew Hermes ("Hermes Report") and provide my comments on the Hermes Report and also on certain other issues resulting from my review. My qualifications as an expert witness are listed in my Curriculum Vitae, which was attached as Ex. 2 to my first two reports. I am being compensated at a rate of \$1000.00 per day.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of the Hermes Report and from the issues resulting from my review and any matters set forth in this report. Documents reviewed and considered in preparing this rebuttal expert report are identified in Ex. 1.

I specifically reserve the right to formulate and offer additional opinions based on any other reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial.

II. REBUTTAL TO THE HERMES REPORT

- A. Regardless of how the Court construes the term "PE," the '446 patent is invalid under 35 U.S.C. § 103 in view of the '688 patent combined with the '802 patent, the DSM brochure and the general state of the art of sutures and ligament and vascular prosthetics

EXHIBIT 7

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

EXHIBIT 8

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Civil No. 04-12457 PBS

Arthrex, Inc.
a Delaware Corporation and

Pearsalls Ltd.,
a Private Limited Company
of the United Kingdom,

Defendants.

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

"Direct intertwining contact" means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"Volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss's, Brian Hallet's, and Dr. Mark Steckel's, and Mr. Donald Grafton's deposition testimony.

A list of the documents that I used in forming my opinions is set forth in Ex. 16.

VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, "in February 1992, had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications."

(Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee's definition includes someone with no education that is relevant to suture design and no suture design experience.